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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AIDS HEALTHCARE FOUNDATION, INC., Plaintiff, v. GILEAD SCIENCES, INC.; JAPAN TOBACCO INC.; JAPAN TOBACCO INTERNATIONAL U.S.A., INC.; AKROS PHARMA INC.; JANSSEN SCIENCES IRELAND UC; AND JOHNSON & JOHNSON, Inc. Defendants.	Case No. 3:16-cv-00443-WHA **JAPAN TOBACCO INC.'S NOTICE OF MOTION AND MOTION TO DISMISS AMENDED COMPLAINT UNDER RULE 12(b)(6); MEMORANDUM OF POINTS AND AUTHORITIES** Hearing Date: June 23, 2016 Hearing Time: 8:00 a.m. Before: Hon. William H. Alsup Courtroom 8, 19th Floor

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE THAT, on June 23, 2016, at 8:00 a.m., or as soon thereafter as counsel may be heard, Defendant Japan Tobacco Inc. will and hereby does move to dismiss the Amended Complaint ("Amended Complaint") of Plaintiff AIDS Healthcare Foundation, Inc. ("Plaintiff") filed on April 11, 2016.

Japan Tobacco Inc. brings this motion pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. By this motion, Japan Tobacco Inc. asks this Court to dismiss Plaintiff's Amended Complaint, and all purported causes of action therein against Japan Tobacco Inc. for failure to state a claim upon which relief can be granted. Because it is evident that further amendment would be futile, Japan Tobacco Inc. seeks dismissal of the Amended Complaint against it with prejudice.

This motion is and will be based on this notice of motion and motion, the following memorandum of points and authorities, the accompanying [Proposed] Order, the Amended Complaint and other pleadings on file in this matter including the reply memorandum Japan Tobacco Inc. expects to file, and such other matters and argument as the Court may properly consider.

Dated: May 16, 2016

NEAL N. BEATON
JEROME W. HOFFMAN
CHARLES L. COLEMAN III
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By: /s/ Jerome W. Hoffman
Jerome W. Hoffman

By: /s/ Charles L. Coleman III
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MEMORANDUM OF POINTS AND AUTHORITIES

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I. LEGAL STANDARD

On a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), all allegations of material facts are assumed to be true and construed in the light most favorable to the non-moving party. *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th Cir. 2009). However, dismissal under Rule 12(b)(6) can be based on "the lack of a cognizable legal theory" or "the absence of sufficient facts alleged under a cognizable legal theory." *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699 (9th Cir. 1990). The principle that a court accepts as true all of the allegations in a complaint does not apply to legal conclusions or conclusory factual allegations. *Ashcroft v. Iqbal*, 566 U.S. 662, 678 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). Further, as stated in *Iqbal*, a claim has facial plausibility only when the Plaintiff "pleads factual content that allows the Court to draw the reasonable inference that the Defendant is liable for the misconduct alleged." *Id*. To show that the Plaintiff is entitled to relief, the complaint must "permit the Court to infer more than the mere possibility of misconduct." *Id.* Here, the Amended Complaint fails to meet that standard and should be dismissed. Because it is evident that the deficiencies in the Amended Complaint would not be curable by amendment, the dismissal should be with prejudice.

II. PLAINTIFF FAILS TO PLEAD FACTS TO SUPPORT A PLAUSIBLE LEGAL THEORY AGAINST JAPAN TOBACCO INC.

Plaintiff fails to state a cause of action against Japan Tobacco Inc. for conspiracy under Section 1 of the Sherman Act because a patent holder is legally incapable of conspiring with an exclusive licensee to violate the antitrust laws. *Levi Case Co., Inc. v. ATS Prods, Inc.*, 788 F. Supp. 428, 431-432 (N.D. Cal. 1992) ("a grant of an exclusive license excludes even the patent holder himself from exercising the rights conveyed by the license. The exclusive license, by itself, does not constitute a legal restraint under the antitrust laws." (omitting internal citations)). In that case, the Court noted that the patent holder, Shea, had conveyed, by exclusive license to Sterling Imperial, rights to its patent and that Shea, by virtue of the exclusive license, could not compete in the manufacture of the duct work covered by the patent. Sterling later granted a sub-license to ATS. Based on these facts, the court found that no agreement between ATS and Shea involving

exploitation of the patent in which they both held an interest could be considered to deprive the marketplace of any "independent sources of economic power previously pursuing separate interest." Thus, the court held that ATS and Shea could not "conspire" in violation of the antitrust laws. *Id*. at 432.

Here the allegation is that Japan Tobacco Inc. by virtue of the alleged March 2005 License Agreement with Gilead, conspired with Gilead to violate the antitrust laws by agreeing to an exclusive patent license with Gilead. Under the authority cited above, such a conspiracy is impossible as a matter of law. Plaintiff's conspiracy allegations against Japan Tobacco Inc. in Count III should be dismissed.

III. PLAINTIFF LACKS STANDING TO SUE TO INVALIDATE THE '219 PATENT

Plaintiff lacks standing to pursue against Japan Tobacco Inc. a claim for declaratory judgment as to Japan Tobacco Inc.'s '219 Patent, as pled in Count I of the Amended Complaint. Declaratory judgment jurisdiction exists only where there is a controversy of sufficient "immediacy and reality" to create a justiciable controversy, *i.e.*, (1) an injury-in-fact, *i.e.*, a harm that is concrete and actual or imminent, not conjectural or hypothetical, (2) that is fairly traceable to the defendant's conduct, and (3) redressable by a favorable decision. *Prasco LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008); *see also MedImmune v. Genentech*, 549 U.S. 118, 127 (2007) (a dispute giving rise to declaratory judgment jurisdiction in the patent context must be "definite and concrete, touching the legal relations of parties having adverse legal interests," such that the dispute is "real and substantial" and "admi[ts] of specific relief through a decree of a conclusive character, ***as distinguished from an opinion advising what the law would be upon a hypothetical state of facts***.") (emphasis added). Here, Plaintiff has failed to allege any concrete, actual or imminent harm to it that is traceable to Japan Tobacco Inc.'s conduct concerning any of the patents identified in Count I of the Amended Complaint. Nor, as explained below, can Plaintiff possibly make any such allegation. Accordingly, Plaintiff lacks standing to seek a declaratory judgment against Japan Tobacco Inc. on the validity of any of the patents identified in this lawsuit.

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Plaintiff has failed to allege any concrete, and actual or imminent harm to it that is traceable to Japan Tobacco Inc.'s conduct concerning the '219 Patent.[1] Nor can Plaintiff possibly make that allegation. The '219 Patent claims methods and compositions including two, three-drug combinations (elivitegravir, TAF and emtricitabine, and elivitegravir, TDF and emtricitabine). By Plaintiff's own admission, Plaintiff purchased from Gilead's authorized distributors the Genvoya® product that embodies that elvitegravir-TAF-emtricitabine combination. Compl. ¶ 27. Under the doctrine of patent exhaustion, the lawful sale and purchase of an article that embodies the substantial features of the patent in question exhausts the patentee's—here, Japan Tobacco Inc.'s—rights and bars the patentee from suing the purchaser for patent infringement. *See, e.g., LifeScan Scotland Ltd. v. Shasta Techs., LLC,* 734 F.3d 1361, 1367 (Fed. Cir. 2013); *see also Quanta Computer v. LG Elec.*, 533 U.S. 617, 638 (2008) ("[a]n authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control post-sale use of the article."). Plaintiff does not allege that its purchases of Genvoya® from Gilead's authorized distributors were unauthorized. And Plaintiff does not allege that there exist any elvitegravir-TAF-emtricitabine combination drug products besides Genvoya® that are within the scope of the '219 Patent as would be required to establish a claim of infringement. (Indeed, Plaintiff's entire basis for alleging antitrust injury here is due precisely to the ***lack*** of a standalone TAF product. *See, e.g.*, Compl., ¶¶ 11, 12, 31.) Furthermore, Plaintiff's new allegations regarding AHF's various activities relating to its alleged intention to manufacture, purchase, import, and/or sell unlicensed TAF drugs (*see* Compl., ¶¶ 33-41, 46-47) do not amount to a showing of "meaningful preparation" for making or using an infringing product. *Cat Tech. v. TubeMaster*, 528 F.3d 871, 881 (Fed. Cir. 2008) ("Although a party need not have

[1] Plaintiff's allegation that it suffers a "reasonable apprehension" that it would face a patent infringement suit from ***Gilead*** were Plaintiff to sell, import, develop, distribute, and/or test an unlicensed or standalone drug containing TAF (Amended Compl., ¶¶ 31-44) is implausible. First, Plaintiff's entire basis for alleging antitrust injury is due precisely to a ***lack*** of any unlicensed or standalone drug containing TAF. *See, e.g.*, Amended Compl., ¶¶ 11, 1231. Second, Plaintiff fails to plead any facts to suggest that Gilead has ever sued Plaintiff for the infringement of any patent, let alone that Gilead intends to sue Plaintiff for the infringement of the '219, '791, '788, '065, and '374 patents specifically mentioned in the Amended Complaint. To the contrary, Plaintiff's Amended Complaint reveals that Plaintiff repeatedly has attempted to provoke Gilead on a variety of unrelated matters, without success. Amended Compl., ¶ 32.

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engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment of non-infringement, there must be a showing of 'meaningful preparation' for making or using that product."). Here, Plaintiff has not alleged any presently infringing activity or any concrete steps towards potentially infringing activity. To the contrary, it is uncertain when, if ever, Plaintiff will engage in any potentially infringing activity. *See, e.g., Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346-50 (Fed. Cir. 2007) (dismissing declaratory judgment counterclaim in 2005 where party anticipated infringing activity to take place in "at least 2010-2012, if ever" and current activities consisted of developing and submitting preliminary information to the FDA). Plaintiff thus faces no harm—whether concrete or conjectural—from the '219 Patent and likewise no injury would be redressed by a declaration of invalidity of the '219 Patent. For at least these reasons, Plaintiff lacks standing to seek declaratory judgment on the validity of the '219 Patent.

IV. PLAINTIFF FAILS TO PLEAD FACTS TO SUPPORT A PLAUSIBLE TYING CLAIM

A. Plaintiff's claims in Count IV, V, VI, and VII must be dismissed for failure to state a claim

The tying allegations in Counts IV, V, VI, and VII should be dismissed as to Japan Tobacco Inc. for failure to state a claim. Plaintiff alleges that Gilead, Japan Tobacco Inc., and Janssen reached an agreement to tie the sale of TAF to the sale of elvitegravir, cobicistat, emtricitabine, and rilpivirine in the United States. Compl., ¶¶ 175, 187, 190, 198. But these allegations are not plausible. By virtue of the License Agreement, Gilead has the exclusive rights to the '219 Patent. Gilead alone controls the marketing of its own anti-viral products in the United States. Further, there is no mention in the 2005 License Agreement or any of its Amendments of any agreement or even a plan to tie the sale of any product patented by Japan Tobacco Inc. to TAF or TDF, and Plaintiff has not alleged otherwise. Thus, Plaintiff's allegations that Japan Tobacco Inc. agreed to any tying arrangement are contradicted by the plain terms of the License Agreement. In any event they are purely conclusory and violate the *Twombly* standard for plausible allegations. *See Invamed, Inc.*, 22 F. Supp. 2d 210 at 222 (S.D.N.Y 1998)("Invamed's bare-boned statement that the

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Affiliates participated in a conspiracy—in the absence of any averments linking the Affiliates to a conspiratorial agreement—is insufficient to state a cause of action against the Affiliates.").

Furthermore, in order to state a tying claim, Plaintiff must allege facts that would establish that the Defendant has market power in a relevant market. *Apple, Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1195 (N.D. Cal. 2008). To demonstrate market power flowing from a patent, a plaintiff must show that, within the relevant market, there are no acceptable substitutes for the patented product. *Orion Elec. Co., Ltd. v. Funai Elec. Co., Ltd.*, No. 01 CV 3501 (AGS), 2002 WL 377541, at *6 (S.D.N.Y. March 11, 2002). Here, Plaintiff's tying claim should be dismissed because Plaintiff's defined relevant product market—"the market for sales of TAF-containing products"—is not supported by any factual allegations.

First, Plaintiff alleges that the relevant product market is "TAF-containing products." Amended Compl., ¶ 120. However, this Court has rejected allegations that an antitrust market can consist of just one single brand for purposes of alleging a tying arrangement. *Apple, Inc.*, 586 F. Supp. 2d at 1198. In *Apple, Inc.*, this Court held that "a manufacturer's own products do not themselves comprise a relevant product market." *Id.* Even in circumstances where brand loyalty is intense, courts reject the argument that a single branded product constitutes a relevant market. *Id.* The Court recognized that antitrust markets consisting of a single brand may exist in "rare and unforeseen circumstances." *Id.* However, after examining the plaintiff's factual contentions under *Twombly*'s pleading standard, this Court concluded that plaintiff failed "to allege facts plausibly supporting the counterintuitive claim that Apple's operating system is so unique that it suffers *no* actual or potential competitors." *Id.* Likewise, here, Plaintiff has failed to allege any facts plausibly supporting the contention that TAF is so unique that it suffers no actual or potential competitors.

Plaintiff alleges that Gilead possesses substantial market power over the sale of TAF, and that, for those seeking to purchase TAF, there is no other option than to purchase it through a product offered by Gilead. Amended Compl., ¶ 178. These allegations are tautological. Naturally, Gilead can exclude others from selling TAF-containing products because it has a valid patent covering TAF. *See Apple, Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1198 (N.D. Cal. 2008) ("A

company does not violate the Sherman Act by virtue of the natural monopoly it holds over its own product."); *see also Green Country Food Mkt., Inc. v. Bottling Grp.*, 371 F.3d 1275, 1282 (10th Cir. 2004). The pertinent question is whether there are acceptable substitutes for TAF in the market. *Orion Elec. Co., Ltd.*, 2002 WL 377541, at *6. Here, Plaintiff has failed to allege any facts to show that there are no acceptable substitutes for TAF in the market.

Plaintiff's theory on market power (Amended Compl., ¶¶ 120-28) is circular and conclusory. For example, Plaintiff alleges that "[a]t competitive price levels, TAF does not exhibit significant positive cross-elasticity of demand with respect to price with any other products." Amended Compl., ¶ 122. But Plaintiff also contends there are no products that compete with TAF-containing products. Amended Compl., ¶ 123. If there are no products that compete with Gilead's TAF-containing products, then there are no "competitive price levels" for comparison.

Plaintiff's attempt in Paragraph 123 to allege facts to show that there are no substitutes for TAF containing products is also circular. That paragraph alleges that, "TAF's pharmacological profile, and thus its side effects and efficacy profile, is different from other medicines used to treat the same or similar conditions." But since TAF is patented, its pharmacological profile would necessarily be unique. Paragraph 123 also alleges that, "TAF has lower incidence of impaired kidney function than tenofovir disoproxil."[2] Simply alleging that one product is better than another for some patients does not give that product market power. Finally, Paragraph 123 alleges that, "[o]ther, non-TAF-containing medicines cannot be automatically substituted for the only TAF-containing products (Genvoya, Odefsey, and Descovy) on the market by pharmacists." This allegation is also circular. A pharmacist cannot by law substitute one drug for another unless it is a generic equivalent medicine. Since TAF has no generic equivalents, no substitution by a pharmacist is permitted. But Plaintiff alleges no facts to support why other drugs cannot be substituted for TAF-containing products by physicians.

Finally, Plaintiff's bare-bones allegation about cross-elasticity of demand is insufficient to state a claim. Similar allegations have been rejected by other courts. For instance, in *Spahr v.*

[2] Tenofovir disoproxil is TDF over which Gilead also has a patent.

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Leegin Creative Leather Products, No. 2:07-cv-187, 2008 WL 3914461 (W.D. Tenn. Aug. 20, 2008), the court granted defendant's motion to dismiss:

> Plaintiffs do allege … that 'Brighton-brand products are distinct products characterized by an inelasticity of demand.' Plaintiffs have not, however, alleged facts which explain their conclusory allegation. This is precisely the type of conclusory allegation the Supreme Court cautioned against in *Twombly*, 127 S.Ct. at 1966.

2008 WL 3914461, at *9 n. 2. Likewise, Plaintiff here provides no factual basis for this bare assertion. Plaintiff's conclusory allegations are insufficient to establish market power in TAF as the tying product.

B. Plaintiff's state law tying claims in Counts V, VI, and VII must be dismissed for failure to state a claim

Plaintiff's state law "tying" claims, included in Counts V, VI and VII, suffer from the same infirmities as its federal tying claims brought in Count IV. Plaintiff's fifth claim for relief arises under California's Cartwright Act. The Cartwright Act was patterned after Section 1 of the Sherman Act, and the pleading requirements under the two statutes are similar. *Apple, Inc.*, 586 F. Supp. 2d at 1203. Likewise, Plaintiff's seventh claim for relief arises under Nevada's Unfair Trade Practices Act, Nev. Rev. Stat. § 598A.060. Like California's Cartwright Act, Nevada's statute tracks the provisions of the Sherman Act. *See Boulware v. State of Nev., Dept. of Human Res.*, 960 F.2d 793, 800 (9th Cir. 1992). Further, the statute adopts by reference the case law applicable to the federal antitrust laws. *See* Nev. Rev. Stat. § 598A.050 ("The provisions of this chapter shall be construed in harmony with prevailing judicial interpretations of the federal antitrust statutes."). Plaintiff's tying claims under California's Cartwright Act and Nevada's Unfair Trade Practices Act fail because Plaintiff has not pled, and cannot plead, a legally-cognizable relevant product market in which Gilead has market power. While Plaintiff alleges that Gilead has "collective market power" over the sale of TAF, as discussed above, Plaintiff has not established market power in TAF as the tying product. For the same reasons as apply to Count IV, Plaintiff's state law antitrust tying claims in Counts V and VII, must be dismissed.

Plaintiff's sixth claim for relief arises under California's unfair competition statute, Cal. Bus. & Prof. Code § 17200. The statute proscribes "any unlawful, unfair or fraudulent business act

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or practice." *Id.* California courts have held that "[i]f the same conduct is alleged to be both an antitrust violation and an 'unfair' business act or practice for the same reason—because it unreasonably restrains competition and harms consumers—the determination that the conduct is not an unreasonable restraint of trade necessarily implies that the conduct is not 'unfair' toward consumers." *Apple, Inc.*, 586 F. Supp. 2d at 1204; *see also Chavez v. Whirlpool Corp.*, 93 Cal.App.4th 363, 375, 113 Cal.Rptr.2d 175 (2001). Here, Plaintiff's contention that Defendants have engaged in an unlawful business act or practice is premised entirely on its contentions that Defendants have violated antitrust laws by "tying the sale of TAF to the sale of elvitegravir, cobicistat, emtricitabine, and rilpivirine." Amended Compl., ¶¶ 190-191. Accordingly, as it relies on the same flawed theory as Count V, Count VI must also be dismissed. *See Aguilar v. Atlantic Richfield Co.*, 25 Cal.4th 826, 866-67 (Cal. 2001) (no § 17200 claim where predicate antitrust law claim dismissed); *RLH Indus., Inc. v. SBC Commc'ns, Inc.*, 133 Cal. App. 4th 1277, 1286, 35 Cal. Rptr.3d 469, 475 (Cal. App. 4 Dist. 2005) ("Having properly granted [Defendant] summary judgment on the Cartwright Act causes of action, the court also properly granted [Defendant] summary judgment on the unfair competition cause of action"); *Chavez v. Whirlpool Corp.*, 93 Cal.App.4th 363, 375-76 (Cal. App. 2 Dist. 2001) ("[C]onduct alleged to be 'unfair' because it unreasonably restrains competition and harms consumers, such as the resale price maintenance agreement alleged here, is not 'unfair' if the conduct is deemed reasonable and condoned under the antitrust laws.").

V. CONCLUSION

Plaintiff has failed to state a claim against Japan Tobacco Inc. The Amended Complaint fails to set forth sufficient facts to support Plaintiff's standing to sue for invalidation of the '219 Patent in Count 1. Additionally, the Amended Complaint alleges an antitrust conspiracy that: (1) is not plausible; and, (2) cannot exist as a matter of law. Finally, the Amended Complaint fails to state a claim against Japan Tobacco Inc. under the federal or state antitrust laws or state unfair competition law, because it fails to allege facts to support a contention that anyone other than Gilead was

involved in any marketing decisions for TAF-containing products or that Gilead has market-power in any properly defined relevant market to support a claim for unlawful tying. [3]

All of these provide independent grounds to dismiss the Amended Complaint with prejudice as to Japan Tobacco Inc.

Dated: May 16, 2016

HOLLAND & KNIGHT LLP

By: /s/ Jerome W. Hoffman
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Charles L. Coleman III

By: /s/ Charles L. Coleman III
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Attorneys for Defendants Japan Tobacco Inc.

ATTESTATION

Pursuant to Civil Local Rule 5-1(i)(3), I hereby attest that concurrence in the filing of Japan Tobacco Inc.'s Notice of Motion and Motion to Dismiss Amended Complaint under Rule 12(b)(6) and Memorandum of Points and Authorities in support thereof has been obtained from the other Signatory. I further attest that I will maintain records to support this concurrence for subsequent production for the Court, if so ordered, or for inspection upon request by a party, until one year after the final resolution of the action (including appeal, if any).

By: /s/ Charles L. Coleman III
Charles L. Coleman III

[3] In addition to the reasons set forth above, Japan Tobacco Inc. also joins the motion to dismiss filed by Gilead Sciences, Inc. on May 16, 2016, and adopts the reasons and arguments set forth therein as further grounds for dismissal of the Amended Complaint.

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